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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/492,763

01/27/00

MASATSUJI

E

Q54487

EXAMINER

HM22/0731

Sughrue Mion Zinn MacPeak & Seas PLLC
2100 Pennsylvania Ave N W
Washington DC 20037-3213

KIM, V

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

07/31/01

Please find below and/or attached an Office communication concerning this application or
proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/492,763

Applicant(s)

MASATSUJI ET AL.

Examiner

Vickie Y. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8 and 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Status of Application

1. Acknowledgement is made of applicant's response filed July 02, 2001. The election of Group I, claims 1-10 and the election of species which has been exemplified in claim 9 are affirmed by applicant. Thus claims 1-6 and 9 are maintained under the consideration for further examination whereas non-elected claims 7-8 (due to non-elected species) and 10-15 are maintained as withdrawn from the consideration.

Declaration under 37 C.F.R. 1.132 acknowledged

2. Declaration under 37 C.F.R. 1.132 filed July 02, 2001 has been carefully considered and acknowledged. Since the declaration has made to attribute the cited reference and to obviate art rejection in previous office action, the declaration necessitated the new ground(s) of rejection presented in this office action as follows. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6 are rejected as being anticipated by Fahim (US 4,372,296) or Schinitisky (US4,938,969) under 35 U.S.C. 102(b).

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The claims 1-6 read on a topical composition comprising a therapeutically effective amount of ascorbic acid derivative and a zinc salt; or a zinc salt of said ascorbic acid derivative.

Fahim or Schinitisky teaches a topical composition required by claims 1-6, comprising zinc salt(e.g. zinc sulfate) and ascorbic acid. Firstly, Fahim('296) teaches ascorbic acid composition that includes therapeutically effective amounts of both zinc salt(1-4%), ascorbic acid (2-6%). Secondly, Schinitisky('969) also teaches a composition comprising zinc salt(0.5-5%) and ascorbic acid(2-20%). See full text , especially column 2, lines 55-58 and claims. Furthermore '296 patent teaches that the patented composition provides a synergistic combination effective as an antimicrobial agent , especially effective in the treatment of acne when they are applied to the skin whether or not they are sonicated into the skin. Each instant claim requires various therapeutic amounts for specific indication such as inhibiting amount for Propionibacterium. Even though the species of microorganism required are different from the species taught by the reference, it could be envisaged that the organisms required would be killed effectively by the patented composition as long as they contain same therapeutic effective amount disclosed in the instant specification (at page 15-17, 0.01-90% with ratio 1:0.1 to 1:10) because it should be inherently effective. See Ex parte Novitski 26 USPQ 1d 1389. All the critical elements required by the instant claims are met by the cited references.

It is also noted that a recitation of the intended use of the claimed invention, in case of the claimed invention is directed to the composition claims, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If therapeutic amount is same for doing different activities, it should be considered as same. In this case, there are no specific differences(limitation recited) required

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by neither claims nor specification. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Thus the claimed subject matter is not patentably distinct over the prior art.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sano et al (US5,516,919) in view of Fahim or Schinitzky et al.

Sano et al teaches a metal salt of ascorbic acid derivative such as magnesium L-ascorbic acid-2-phosphate and a process of making the composition. Sano also teaches that the patented composition has enhanced therapeutic effects and good stability which is effectively used in various skin disorders (see full text, especially claim).

It fails to exemplify zinc salt of L-ascorbic acid phosphate as final product.

However it would have been obvious to any ordinary skilled artisan to extend Sano's teaching to make zinc salt of L-ascorbic acid phosphate when it is taken in view of Fahim or Schinitzky because Fahim or Schinitzky teaches the value of zinc salt in ascorbic acid composition when it is applied in the treatment of skin conditions. Fahim or Schinitzky, as

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mentioned earlier, emphasizes that the combination of ascorbic acid and zinc salt enhances efficacy synergistically and improves the stability as well. For instance, US'969 states that zinc sulfate is essential ingredient in ascorbic acid composition because there is no beneficial effect without zinc sulfate(see column 2, lines 55-58). Especially one would have motivated to do so with reasonable expectation of success because Sano teaches the technique to make metal salt of ascorbic acid-2-phosphate using zinc sulfate or zinc carbonate, in addition to the benefit of combination product such as improved therapeutic efficacy and stability. Even though Sano did not exemplify or was silent about final product of zinc salt L-ascorbic acid -2-phosphate, one would formulate the zinc salt of L-ascorbic acid 2-phosphate without difficulties when Sano's preparation has been learned (see column 4, lines 10-column 6, lines50). Thus zinc salt of L-ascorbic acid-2-phosphate is prima facie obvious and not patentably distinct over the prior art.

Conclusion

7. Claims 1-6 and 9 are maintained as rejected.
8. Claims 7-8 and 10-15 are withdrawn from consideration.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM) and Fax number is (703) 746-3165.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

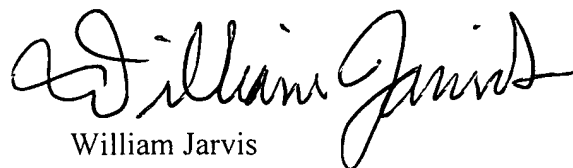
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Vickie Kim,
Patent examiner
July 24, 2001

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William Jarvis
Primary examiner
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